UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,050	02/20/2002	David W. Osborne	359872001400	2420

21186 7590 10/17/2007
SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER
CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
10/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/081,050	OSBORNE, DAVID W.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,7-22 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,7-22 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of RCE dated 8-3-07 is acknowledged.

Claims 1, 4, 7-22 and 25 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8-3-07 has been entered.

The following rejection of record has been maintained:

Claim Rejections - 35 USC § 102

1. Claims 1, 4, 7, 13, 14, 20, 21 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,060,085 ('085) to Osborne or US 5,863,560 ('560) to Osborne (as evidenced by Russell, AFP, 2000).

Instant claim 1 recites a method for reducing the number of non-inflammatory acne lesions comprising the step of topically applying a composition consists essentially of dapsone. Claim 25 is directed to a method of treating non-inflammatory acne lesions comprising the step as in claim 1.

'085 and '560 discloses topical therapeutic compositions for the treatment of acne. The composition is in the form of semi-solid aqueous gel, where in the pharmaceutical is dissolved and in microparticulate form (col. 2, summary of invention-

both '085 and '560). Particularly, Osborne discloses that the composition is effective with dapsone as an active agent (col. 3 of '085 and '560). Examples 2-6 in col. 9-11 (both the references) recite compositions containing dapsone, with other cosmetic additives such as methylparaben, which reads on claimed preservative. Table 1 (col. 13, both patents) recite 3% dapsone concentration. Both references disclose dapsone in a topical composition and for the same purpose i.e., treatment of acne.

Russell teaches that acne, usually diagnosed by the patient, is of three type i.e., inflammatory acne, non-inflammatory acne or a mixture of both (inflammatory and non-inflammatory) types and that the most common situation of acne is a mixture of both inflammatory and non-inflammatory (page 3, clinical manifestations & Figure 5, management of acne on page 10). While '085 and '560 does not disclose treatment of non-inflammatory acne, nothing in the above references indicate that acne (treated by Dapsone of '085 or '560) is not the commonly occurred form (as taught by Russell) and that the acne lesions are only of inflammatory type. Accordingly, both inflammatory and non-inflammatory lesions are inherent to the acne described in the teachings of '060 and '560 and therefore the claimed method of reducing the number of non-inflammatory lesions and the treatment of non-inflammatory lesions of acne is inherent to the teachings of '085 and '560.

2. Claims 8-12, 15-19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,060,085 in view of Russell, as applied to claims1, 4, 7, 13, 14, 20, 21 and 25 above, and further in view of US 6,200,964 to Singleton et al OR over US

5,863,560 ('560) in view of Russell, as applied to claims 1, 4, 7, 13, 14, 20, 21 and 25 above, and further in view of in view of Russell and US 6,200,964 to Singleton et al.

'085 and '560 fail to teach the claimed cream, lotion, spray, suspension and ointment formulations. The above references also fail to teach 5% dapsone. Russell suggests preparation of acne treatment formulations in the form of a gel, ointment or cream depending on the patient's skin type (page 3).

'964 teach acne treatment composition comprising salicylic acid as an active agent for the treatment and prevention of acne (col. 1). '964 teach addition of active agents such as sunscreens, antioxidants, fragrances etc., (col. 4) and teach the composition in the form of spray, cream, lotion, suspension, gel etc (col. 7, lines 20-31). '964 further teach addition of dermatologically active agent such as dapsone in the composition. It would have been obvious to one of an ordinary skill in the art at the time of the instant invention to prepare the dapsone compositions of '085 or '560 in the form of a spray, lotion or a cream or an ointment, depending the type of the skin of the patient being treated because '964 teaches acne preparations in any of the above forms and Russell suggests creams are appropriate for dry skin, gels for oily skin, lotions for any skin type and solutions fro dissolved topical antibiotics. Accordingly, it would have been within the scope of a skilled artisan to optimize the amount of dapsone (of '085 and '560) and choose the type of the formulation i.e., a gel or a lotion or a cream etc., depending on the type of skin and also depending on the solubility of the compound, with an expectation to achieve the desired effect (treatment of acne lesions- both types).

Response to Arguments

Applicants have not presented any arguments along with the RCE. Accordingly, the following examiner's response to applicants' arguments of 12-12-06 has been presented again.

Applicant's arguments filed 12-12-06 have been fully considered but they are not persuasive.

Rejection of claims under 35 USC 102(b):

Claims 1, 4, 7, 13, 14, 20, 21 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,060,085 to Osborne or US 5,863,560 to Osborne (as evidenced by Russell, AFP, 2000).

Applicants argue that the Examiner's theory of inherency is misapplied and that if topical dapsone of Osborne had actually been used to treat inflammatory acne, the examiner would be correct in stating that dapsone (of Osborne) would inherently treat non-inflammatory acne. It is argued that there was no actual use of dapsone by Osborne in treating any kind of acne, and therefore inherency cannot attach. In this regard, applicants state the two general principles for inherency that require actual use i.e., alleged feature necessarily occurs each and every time the prior art composition or method is used and that the newly discovered feature is inherent if the applicant claims the same use described for a prior art composition or method but asserts patentability by additionally claiming the new feature of that composition or method.

Applicants' arguments are not persuasive because in contrast to what is argued Osborne clearly states that the composition is specifically used to treat inflammatory acne and courts have concluded that applicant need not have actually reduced the invention to practice prior to filing. Gould v. Quigg, 822 F.2d 1074, 1078, 3 USPQ 2d 1302, 1304 (Fed. Cir. 1987). This, together with the fact that Osborne (admittedly) teaches dapsone for treat inflammatory acne only supports the two principles of inherency cited (above) by applicants. More specifically, the old method of treating

inflammatory acne with dapsone (Osborne) anticipates the claimed new use of treating non-inflammatory acne. Secondly, the fact that Osborne anticipates claimed method is supported by Gould v. Quigg, 822 F.2d 1074, 1078, 3 USPQ 2d 1302, 1304 (Fed. Cir. 1987), which states that actual use is not required when a reference teaches the composition or method.

With respect to the argument regarding the enablement of the teachings of Osborne, if applicants emphasize that it is not an enablement issue, then examiner once again reiterates that every patent is presumed valid (35 U.S.C. 282), and that presumption includes the presumption of operability (Metropolitan Eng. Co. v. Coe, 78 F.2d 199, 25 USPQ 216 (D.C.Cir. 1935) and that applicants need not have actually reduced the invention to practice prior to filing. Further, with respect to the argument regarding examples, the specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. In re Borkowski, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970). Both '050 and '085 disclose the exact compositions containing dapsone, as claimed and disclose the use (applicants admitted on record) the composition for acne (col. 3, lines 12-17).

Applicants' arguments regarding the provisions of 35 USC 101 "new and useful patents" is acknowledged. However, under the principles of inherency, if a prior art device is the same as that described in the application for a patent, it can be assumed that the device will inherently perform the claimed process. See MPEP 2112.02 and In re King, 801, F.2d 1324, USPQ 136 (Fed. Cir. 1986). Examiner notes that applicants

also stated the same case law to prove that principles of inherency do not prohibit a process patent for a new use of an old structure. However, a careful review of the above (In re King in MPEP 2112) reveals that Federal circuit upheld the decision that the prior art inherently performs the function disclosed in the method claims on appeal when the device is used in "normal and usual operation". In this regard, Osborne references teach the "treating inflammatory acne", which can be construed as the usual and normal operation and that dapsone treats non-inflammatory acne is inherent to the above teachings. Examiner presents the same position with respect to applicants' arguments on pages 9-11 of the response (where applicants argued the case laws of In re May, In re Best and In re Crish).

Applicants insist that Osborne does not actually use dapsone to treat acne and hence the examiner's syllogism of inherency is inappropriate. However, applicants have not provided any experimental evidence to contradict the teachings of Osborne that dapsone is effective in treating inflammatory acne. With respect to the opinion declaration of Robert Lathrop (submitted in response to the action dated 3-16-04), applicants do not deny the fact that the most common forms of acne comprises both inflammatory and non-inflammatory. In fact, on page 9 of the response, applicants clearly admit that Osborne disclosure does not have to show any experiments for it to be enabled. However, even if examiner position regarding applicants' question of enablement of Osborne is true, the same (i.e., that applicants need not have actually reduced the invention to practice prior to filing) is true for inherency situation (as

evidenced by Gould v. Quigg, 822 F.2d 1074, 1078, 3 USPQ 2d 1302, 1304 (Fed. Cir. 1987) and every patent is presumed valid (35 U.S.C. 282).

Applicants state that examiner's statement regarding the instant claims not excluding inflammatory acne appears to be an invitation to amend claims, which is not the case. However examiner has not indicated any amendment such that the instant claims are allowable.

Obviousness rejection:

Claims 8-12, 15-19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,060,085 in view of Russell OR over US 5,863,560 ('560) in view of Russell, as applied to claims1, 4, 7, 13, 14, 20, 21 and 25 above, and further in view of US 6,200,964 to Singleton et al.

With respect to the rejection of claims 8-12 and 15-19 as being unpatentable over Osborne in view of Russell and Singleton, applicants argue that examiner implicitly carried over the inherency argument. Applicants reiterate that there is no inherent ability of dapsone to reduce non-inflammatory acne, which precludes a finding of obviousness under 35 USC 103. It is argued that Russell and Singleton fail to disclose dapsone and that nothing in Osborne or the knowledge generally available in the art would lead one to treat non-inflammatory acne with dapsone. Therefore, it is argued that there is no suggestion or motivation to combine the teachings to use dapsone for non-inflammatory

acne, and there would be no reasonable expectation of success in reducing non-inflammatory lesions. Applicants' arguments regarding the inherent ability of dapsone to reduce non-inflammatory acne have been adequately addresses in the previous paragraphs. Applicants state that inherency has no place in obviousness and cites In re Shetty, 195 USPQ 753 (C.C.P.A. 1977). However, the combination of references cited here is not for the claimed method and instead for the claimed forms of the composition i.e., cream, lotion, spray etc. The motivation to prepare the composition in the form of gels, lotions etc., depending on the skin type being treated comes from the teachings of Russell and also from the teachings of Singleton. Therefore, it would have been obvious to one of an ordinary skill in the art at the time of the instant invention to prepare the dapsone compositions of '060 or '560 in the form of a spray, lotion or a cream or an ointment, depending on the type of skin and also depending on the solubility of the compound, with an expectation to achieve the desired treatment of acne lesions (both types).

Additionally, examiner's response from the advisory action dated 5-25-07 (in response to applicants' arguments of 5-10-07) is repeated here:

In response to the argument that there was no actual use of dapsone by Osborne for treating acne, Osborne clearly emphasizes that the invention is directed to treat acne (C 3, L 12-16). Further, Osborne references state that in order to treat inflammatory lesions, the active agent has to penetrate past the stratum corneum (C2, L 5-15) and teaches a composition that contains active agent, dapsone, such that one form of

dapsone is able to cross stratum corneum to treat inflammation and another form of dapsone (in the same composition) that does not cross stratum corneum. Thus, the composition of Osborne provides treatment for both inflammatory acne and non-inflammatory acne. In response to the argument that in treating inflammatory acne, one does not smear the medication over the entire surface of the skin, applicants have neither provided evidence that one does not specifically choose inflammatory acne nor instant claims recite exclusion of inflammatory acne. It is implicit that inflammatory and non-inflammatory lesions co-exist and prior art teaches same compound for the same condition (acne), and furthermore, teaches one part of the composition that is exclusively for crossing stratum corneum and another for above stratum corneum. Accordingly, if applicants' assertion that instant invention is effective for treating acne then for the same reason the formulation of Osborne references is inherently effective. A close review of the instant specification (page 5, 0020) shows that instant composition possess the same mechanism as that described in the cited references i.e., partitioning out of the microparticulate dapsone out of the stratum corneum, thus providing a reservoir capacity in the supra corneum zone (above stratum corneum). Thus, as explained in the previous action, the ability to treat non-inflammatory lesions of acne is inherent to the composition of Osborne.

For claims 8-12, 15-19 and 22, applicants' arguments are not persuasive because even though the claims are directed to a method, the active agent responsible for acne treatment is taught by Osborne references and it is for the form of the composition i.e., lotions, sprays etc., that the teachings of singleton has been combined.

Conclusion

This is a Continuation of applicant's earlier Application No. 10/081,050. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AU 1615
October 13, 2007

LAKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER